

### **REMARKS**

Prior to entry of this preliminary amendment, claims 20-29, 31-41, 48-50, 58 and 59 are pending in the subject application. Claims 20-29, 31-41, 48-50, 58 and 59 are canceled herein and new claims 61-82 added. Support for the new claims can be found throughout the specification as filed.

### **35 U.S.C. §103 REJECTIONS**

#### **Motamedi and Swanson**

Claims 20, 21, 24-29, 31, 32, 37-41, 48-50, 58 and 59 stand rejected over Motamedi et al. [USP 6,143,019; “Motamedi”] in view of Swanson [USP 6,023,638; “Swanson”].

Because the previously pending claims are canceled herein, Applicants will address the new pending claims in relation to Motamedi and Swanson.

Applicants’ claim 61 provides a non-thermal method for treating and/or curing cardiac arrhythmias. Applicants’ method comprises administering a photosensitizing agent to at least one pulmonary vein; inserting an illumination device into the at least one pulmonary vein ostia before, during, or after administration of the photosensitizing agent; and during and/or after the photosensitizing agent is administered, using the illumination device to activate the photosensitizing agent in the pulmonary vein, thereby ablating a section of the pulmonary vein and electrically isolating the pulmonary vein from the left atrium.

Applicants respectfully submit that Motamedi and Swanson, alone and in combination, at least fail to teach or suggest such a method wherein photosensitizing agent is administered to at least one pulmonary vein and wherein an illumination device is used to activate the photosensitizing agent to thereby ablate a section of the pulmonary vein and electrically isolate the pulmonary vein from the left atrium.

Motamedi describes a device and method for treating cardiac arrhythmias. According to Motamedi, heating and thus coagulating (“ablating”) of myocardial tissue responsible for cardiac

arrhythmias has been shown to be of great therapeutic value. Motamedi's device and method are specifically designed for the ablation or modification of these tissues. (See col. 1, lines 16-17 and 29-32)

According to Motamedi, previous heating instruments are inadequate for ablating such deep tissues where arrhythmias arise because, with these instruments, the ablation "tip does not directly reach deep intramyocardial tissue where arrhythmias may arise" (col. 1, lines 57-62). To overcome these inadequacies, Motamedi developed a device and method for "directly heating the heart" (col. 2, lines 33-34) by "intramyocardial delivery of diffused laser light, or other ablating energy" (col. 2, lines 55-56). According to Motamedi's method, the tissues involved in the arrhythmia are identified, the distal end of the conductor extended past the distal end of the catheter and into the tissue, and ablating energy transmitted through the conductor into the tissue. (see col. 3, line 67-col 4, line 3). As set out, "When the distal end 24 of the catheter 22 is in the desired position, the tip 42 \* \* \* is extended past the sheath 36 a predetermined distance, puncturing the endocardium 30 and extending 62 into the myocardial tissue 32" (col. 8, lines 28-32).

Thus, Motamedi is specifically directed towards devices and methods for ablating deep myocardial tissues by puncturing the endocardium, extending the ablating energy source into the myocardial tissue, and directly heating the deep myocardial tissue. Further Motamedi's method and device is specifically directed towards heating the myocardial tissue responsible for the arrhythmia.

Thus, Motamedi does not teach or suggest a method wherein the device is positioned within the pulmonary vein ostia (the passageway of the pulmonary vein) during ablation – Motamedi requires positioning within the deep myocardial tissue. Further Motamedi does not teach or suggest a method wherein the pulmonary vein is ablated – Motamedi specifically ablates the deep myocardial tissue responsible for the arrhythmia.

Further, as previously discussed, while Motamedi recites the terms “photodynamic processes” and “photodynamic therapy”, Motamedi does not teach or suggest any guidelines as to how such a method could be used or carried out to ablate a pulmonary vein.

Swanson does not remedy these deficiencies in Motamedi. Swanson describes a system and method for temporarily stunning a zone of tissue, for example, tissues of the heart, temporarily rendering it electrically unresponsive (Abstract). This enables a physician to easily identify the tissue that is intended for modification as well as tissue that is not (col. 3, lines 54-65). A common electrode can be used to both temporarily render tissue unresponsive as well as modify the tissue by varying the energy applied to the tissues.

Swanson is specifically directed towards the application of RF energy to thermally stun and modify tissue. Swanson does not at all mention photodynamic therapy nor does Swanson teach or suggest if or how photodynamic therapy could successfully be used to ablate the pulmonary veins.

Applicants note that photodynamic therapy emerged as a method for treating cancer. Such therapy involves the delivery of a photosensitizing agent, which is selectively accumulated and retained in neoplastic tissue (abnormal new growth of tissue, e.g. a tumor) relative to normal tissue. The photosensitizing agent is then activated to destroy the neoplastic tissue, in which the agent selectively accumulated.

Applicants respectfully submit that there is no teaching or suggestion in Motamedi or Swanson to use photodynamic therapy to ablate the pulmonary vein, which is not responsible for the arrhythmia and which does not contain neoplastic tissue. Motamedi is specifically directed towards destroying the tissues responsible for arrhythmias (not the pulmonary veins), while Swanson does not deal at all with photodynamic therapy, much less that it could be used to ablate the pulmonary vein (which does not contain neoplastic tissue). Clearly, the combined teachings of Motamedi and Swanson would not have suggested Applicants' invention absent impermissible hindsight reasoning.

Accordingly, Applicants respectfully submit that claim 61 is patentable over Motamedi and Swanson. Claims 62-82 depend from claim 61 and, likewise, are patentable over Motamedi and Swanson. Reconsideration and withdrawal of the rejection is respectfully requested.

**Motamedi, Swanson, and Altman**

Claims 22 and 23 are rejected under 35 U.S.C. §103(a) in view of Motamedi, Swanson, and Altman.

Because the previously pending claims are canceled herein, Applicants will address the new pending claims in relation to Motamedi, Swanson, and Altman.

As set out above, Motamedi and Swanson fail to teach or suggest a method wherein photosensitizing agent is administered to at least one pulmonary vein and wherein an illumination device is used to activate the photosensitizing agent to thereby ablate a section of the pulmonary vein and electrically isolate the pulmonary vein from the left atrium.

Altman does not remedy these deficiencies.

Altmann generally indicates that atrial fibrillation can be treated by ablation of the junction of the pulmonary veins. However, Altman does not teach or suggest how this is or can be accomplished. Rather, Altman describes a device and method for temporarily inhibiting electrical impulses in the pulmonmary vein, which allows a user to determine whether the fibrillation would cease occurring of the vein was ablated. Altmann does not teach or suggest that photodynamic therapy can be used to ablate the pulmonary vein and, if it can be successfully used to ablate the pulmonary vein, how this could be done.

Clearly, the combined teachings of Motamedi, Swanson, and Altman would not have suggested Applicants' invention absent impermissible hindsight reasoning.

Accordingly, Applicants respectfully submit that claim 61 is patentable over Motamedi, Swanson, and Altman. Claims 62-82 depend from claim 61 and, likewise, are patentable over

Motamedi, Swanson, and Altman. Reconsideration and withdrawal of the rejection is respectfully requested.

**Motamedi, Swanson, and Leone**

Claims 33-36 are rejected under 35 U.S.C. §103(a) in view of Motamedi, Swanson, and Leone.

Because the previously pending claims are canceled herein, Applicants will address the new pending claims in relation to Motamedi, Swanson, and Altman.

As set out above, Motamedi and Swanson fail to teach or suggest a method wherein photosensitizing agent is administered to at least one pulmonary vein and wherein an illumination device is used to activate the photosensitizing agent to thereby ablate a section of the pulmonary vein and electrically isolate the pulmonary vein from the left atrium.

Leone does not remedy these deficiencies.

Leone describes a photodynamic therapy balloon catheter that is specifically designed so as to provide a greater degree of light illumination uniformity.

However, Leone does not teach or suggest that photodynamic therapy could be used to treat and/or cure cardiac arrhythmias or how this could be accomplished.

Clearly, the combined teachings of Motamedi, Swanson, and Leone would not have suggested Applicants' invention absent impermissible hindsight reasoning.

Accordingly, Applicants respectfully submit that claim 61 is patentable over Motamedi, Swanson, and Leone. Claims 62-82 depend from claim 61 and, likewise, are patentable over Motamedi, Swanson, and Leone. Reconsideration and withdrawal of the rejection is respectfully requested.

**CONCLUSION**

Applicant respectfully requests early consideration and allowance of the subject application.

Applicants believe that additional fees are not required in connection with the consideration of the within matter. However, if for any reason a fee is required, a fee paid is inadequate or credit is owed for any excess fee paid, you are hereby authorized and requested to charge Deposit Account No. **04-1105**.

Should the Examiner wish to discuss any of the amendments and/or remarks made herein, the undersigned attorney would appreciate the opportunity to do so.

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Respectfully submitted,

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